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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,841	04/20/2006	Harry Leneau	P00902-US-01	7450

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ICE MILLER LLP
ONE AMERICAN SQUARE, SUITE 3100
INDIANAPOLIS, IN 46282-0200

EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
10/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,841	LENEAU ET AL.	
	Examiner	Art Unit	
	DEBBIE K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are presented for examination on the merits.

The request for status papers filed July 24, 2009, October 22, 2007 as well as November 15, 2006 and November 15, 2006, have all been received and are noted.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 24, 2006, was filed and received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/16977 (WO) in view of Hies et al (USP 5147548), and FRENCH ENGLISH ABSTRACT, and Hodgkinson (USP 6616927), noted on the enclosed PTO-892 Form and *previously* enclosed PTO-1449 Form of July 24, 2006.

Claims are drawn to a composition comprising sterile bovine colostrum by filtering colostrum while retaining antibodies, sterilizing the colostrum and packaging the colostrum in a syringe; and methods of preparing and using for treating animals for disease, therefore.

WO teaches a composition and method of preparing a sterile bovine colostrum that has been highly filtered by filtering (e.g. ultrafiltration) colostrum to remove large components while retaining antibodies, sterilizing the colostrum and providing in liquid form. Note abstract and page 4, lines 4-9 and lines 23-31. Raw colostrum is disclosed.

Hies et al teach a sterilized colostrum, method of producing it and providing it to a bovine, see entire document and the abstract, all lines. Also note that that steps of filtering and sterilizing are disclosed, see column 3, lines 26-28, wherein the filter size is 5 micron, and a series of filters is disclosed. Also at column 1, lines 40, gamma radiation treatment is disclosed.

FRENCH ENGLISH ABSTRACT teaches colostrum prepared from bovines that has been provided and packaged in injectable form and further comprising a carrier suitable for injection. See the abstract, all lines.

Hodgkinson et al teach injecting cows (e.g. warm-blooded bovine mammals) with colostrum or immunoglobulins obtained therefrom and the desire in the art to protect a calf (e.g. a juvenile) or calves against disease. The injection can have a saline carrier. Note column 2, lines 1-50. The colostrum is obtained from an animal of the same species as the warm-blooded mammal, note the abstract too.

Claims differ from WO in that sterile bovine colostrum has not been provided in injectable form and is not disclosed to be useful for providing a calf with protection by injecting the animal with the colostrum, not packaging the same in injectable form.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the bovine colostrum of WO by using the steps of Hies et al in an injectable form and packaged the same, as disclosed by FRENCH ENGLISH ABSTRACT, and also carrying out the injecting of calves as disclosed by Hodgkinson et al for an animal's protection from disease using sterile bovine colostrum. Each of the claimed features are disclosed or are suggested by the cited prior art teachings.

Ultrafiltration clearly provides for a highly filtered colostrum as well as a sterilized colostrum. In addition, gamma radiation is clearly taught to be used for sterilizing colostrum. To treat an animal with more than one dose of colostrum via subcutaneous injection is well within the purview of an ordinary artisan. A carrier suitable for injection in a syringe, as are the steps of filtering, sterilizing and packaging and injecting an animal for protection from disease are all clearly disclosed by the cited prior art. Each

of the claimed dependent features are clearly disclosed or are at least suggested by the cited teachings of the art, noted above.

In the absence of persuasive evidence to the contrary one of skill in the art would have been motivated to provide for a sterile bovine colostrum as claimed because the cited prior art teaches in combination the claimed sterile bovine colostrum in injectable form and the steps for preparing the same. The method for providing an animal protection from disease comprising injecting the animal with a dose of colostrum is clearly disclosed or at least suggested by the cited prior art combination. The claims are prima facie obvious because each of the claims are disclosed in the cited prior art and one of skill would have been motivated to provide for the same since there would have been an expectation of successful results.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed and previously PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the *previously* enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah K. Ware/

Deborah K. Ware

EXAMINER, ART UNIT 1651